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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS-2008-0023]

RIN 0579-AC31

Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal.

SUMMARY: We are withdrawing a proposed rule that would have amended the regulations regarding the introduction (importation, interstate movement, and environmental release (field testing)) of certain genetically engineered organisms. We are doing this in light of the experience we have gained over the past 28 years, continuing advances in biotechnology, and comments we received on the rule. We will begin a fresh stakeholder engagement aimed at exploring alternative policy approaches. This engagement will begin with a series of webinars that will provide the stakeholder community an opportunity to provide initial feedback.

Information on these webinars will be announced in the coming month.

DATES: Effective [Insert date of publication in the Federal Register], the proposed rule published on October 9, 2008 (73 FR 60008), is withdrawn,.

FOR FURTHER INFORMATION CONTACT: Mrs. Chessa Huff-Woodard, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1236; (301) 851-3943.

SUPPLEMENTARY INFORMATION:

Background

On October 9, 2008, the Animal and Plant Health Inspection Service (APHIS) published in the Federal Register a proposal¹ (73 FR 60008-60048, Docket No. APHIS-2008-0023) to amend the regulations regarding the introduction (importation, interstate movement, and environmental release (field testing)) of certain genetically engineered (GE) organisms in response to advancements in biotechnology and APHIS' accumulated experience in implementing the current regulations. The proposed revisions were extensive and included significant changes to the scope of the regulations and the mechanics of APHIS' regulatory oversight. These changes included aligning the regulations with provisions of the Plant Protection Act (7 U.S.C. 7701 et seq.) and eliminating the current notification and permitting procedures and developing a multiple-category permitting system in its place.

APHIS sought public comment on the proposal from October 9, 2008, to June 29, 2009. We received over 88,300 comments by the close of the comment period. These were received in 5,580 submissions that included unique comments, form letters, and signatories to petitions. We thoroughly reviewed each comment we received. Comments were from a variety of stakeholders, including advocacy groups; State, Tribal, and foreign governments; university researchers; farmers, businesses, trade associations and other regulated entities; and private

¹ To view the proposed rule, supporting documents, and comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0023>.

citizens. We wish to thank the commenters for sharing their knowledge and views on this important subject.

Many commenters indicated that the proposed scope and many of the provisions of the rule were unclear. With regard to the scope of the proposed changes, some commenters asserted that APHIS regulations needed to be more rigorous and far-reaching, while others believed that the proposed regulations were overly restrictive. Other commenters indicated that they were not clear as to what would and would not be regulated, and raised concerns regarding what future criteria might be used to determine what organisms would fall under APHIS regulatory jurisdiction. Concerns regarding oversight of crops that produce pharmaceutical and industrial compounds and increased regulatory burden are just a few examples of the complex issues raised by commenters.

Many commenters also expressed opposition to genetic engineering in general and expressed concerns with a wide range of issues, many of which were outside the scope of the proposed rule. For example, commenters stated that APHIS should consider non-safety based risks, such as economic and social impacts, including impacts on the marketability of non-GE products. Other commenters requested that APHIS regulations include provisions related to the labeling of GE products and raised concerns regarding health effects of GE products and increased pesticide use.

Based on the experience we have gained over the past 28 years, continuing advances in biotechnology, and the scope of comments received on the proposed rule, we have decided to withdraw it and to begin a fresh stakeholder engagement aimed at exploring alternative policy

approaches. Because of rules limiting ex parte² communications with respect to active rulemakings, publication of the 2008 proposed rule has constrained our ability to talk about alternatives with stakeholders. Withdrawing the proposed rule will lift this constraint and provide for a more timely and transparent dialogue. Once it is withdrawn, the nature of our conversations with stakeholders can change, allowing APHIS to discuss regulatory issues in ways that were not possible while the proposal was in formal rulemaking. Our intention is to utilize an open and robust policy dialogue to drive the development of a forward-looking rule that will provide a foundation for our future regulatory activities.

Therefore, we are withdrawing the October 9, 2008, proposed rule. As we explore a full range of policy alternatives, we will consider the comments we received on the proposed rule, as well as new scientific knowledge whenever it is available, and continue to seek the active and open input of stakeholders. In the coming months, we will engage stakeholders on biotechnology regulation alternatives to ensure the safe environmental release (field testing), interstate movement, and importation of certain GE organisms regulated under 7 CFR part 340. Plans for that engagement are underway and will begin with a series of webinars that will provide the stakeholder community an opportunity to provide initial feedback. Information on these webinars will be announced in the coming month and will be available on the APHIS Web site³. For those interested in additional information in advance of the webinars, this will be one

² Ex parte rules are designed to prevent unequal access or the perception of favoritism during the active rulemaking period occurring after a new rule is proposed.

³ Information on upcoming webinars will be available at http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology!/ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzd3V2dDDz93HwCzL29jAyMTIEKIvEo8DYITr-zu6OHibmPgYGBiYWRgaeLk4eLuaWvgYGnGXH6DXAARwNC-sPl_o_AqAfKArACfE8EK8LihIDc0NMlg0xMA5AbGNw!!/?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_biotechnology%2Fsa_news%2Fct_news.

of many topics at an upcoming U.S. Department of Agriculture workshop⁴ on coexistence that is being held on March 12-13, 2015, and will be made widely available via webcast.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 27th day of February 2015.

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

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⁴ Call-in and Webcast information is available at the agricultural coexistence workshop Web page at: http://www.aphis.usda.gov/wps/portal/aphis/newsroom/stakeholder-info!/ut/p/a1/nVFNU4MwEP0tHjxmEkgk4Ug7foBKD9W25MJskyixFChEx_57gem1aN3bzt739u1bLPEGywq-7Ds4W1dQDr0MchYL36fEj8ULFyQi8zBZxCtC6E0PyHoAOVMRGfnJ4sH3Zj3_fhnekjhd3T2LJ04fZwFeY4mlqlzjCpxBU9guV3XITOXy0m5baI_XpIMctvWny8f52HcOdqaoS23ablBolNU4CxljRocaBYp6iCnOkdAAiAPVEBiujQcnxxOWfrl4dDyhkPATYCKUrPfAzy5JAry88KjkD3-yH4eDjPq0h3y_Hd78M-5m_7oX9Ih2b2mKZHb1A2VTHxo!/?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_about_aphis%2Fsa_stakeholders%2Fct_coexistence_meeting. A notice announcing the workshop was published on February 3, 2015 (80 FR 5729-5731, Docket No. APHIS-2013-0047).